FAQ for Investigators with a Dual Appointment at Minneapolis VA and the University of Minnesota – IRB

The following has been put together with input from leaders at both Minneapolis VA Health Care System (MVAHCS) IRB and University of Minnesota IRB and is accurate to the best of our knowledge. Please always follow the instructions in your approval letters and contact the IRB staff individually to get answers for your particular situation.

1. Will I need to get IRB approval at both UMN & MVAHCS?

Due to the nature of your dual appointment, you will likely need IRB approval at both sites if your work includes human subjects research (defined at 45CFR46.102(e)).

2. How should I reflect this need for approval from both IRBs in my proposal?

The proposed research will be reviewed by both the Minneapolis VA Health Care System IRB as well as the University of Minnesota IRB as indicated by the PI's dual appointment at both organizations. See Question #3 for single IRB questions.

3. What if my funding agency requires the use of a single IRB?

The University of Minnesota IRB may not rely upon a VA IRB, nor may the VA IRB rely upon University of Minnesota IRB. As a federal agency, the VA IRB may seek an exception to the Single IRB (sIRB) requirements under 45CFR46.114(b)(2)(ii) when suitable. Your IRB plan should be decided at proposal time, but the exception should be in place prior to submission to either IRB. Contact the Minneapolis VA IRB at IRBMN@VA.GOV to discuss and/or obtain the single IRB exemption.

4. Can I submit my applications to both organizations at the same time? If not, in what order should they be done?

It is recommended that IRB submissions are sequential and that the selection of which IRB reviews first should be guided by where the majority of study activities with participants will occur. Concurrent submissions are possible, however be advised a request to revise a protocol, informed consent document, or other documents made by one IRB may affect the documents submitted to the other IRB.

We highly recommend being very clear in your protocol if only limited work is being done at the University of Minnesota. The best practice is to use the location selection feature in ETHOS and select other and fill in Minneapolis VA in the location text box.

Protocol templates are available to ensure your proposal as complete and compliant as possible.

5. When should I start my IRB submission? How long will it take?

The Investigator Manual (HRP-103) includes updated guidance on submission requirements to comply with National Institutes of Health (NIH) and National Science Foundation (NSF) Just In Time (JIT) requests. The UMN IRB will no longer accept incomplete IRB applications in response to JIT notifications. Additionally, the UMN IRB will not issue "provisional approval" or "approval in concept" letters. Researchers must submit a complete application, including a protocol and all supporting materials.

The JIT notice usually includes a request for content that was not included in the initial application, including certification of IRB approval of the project's proposed use of human subjects. As the title suggests, the time frame for providing this documentation is short and, if you haven't begun your IRB application process, you will likely not have adequate time to do so. Researchers are encouraged to begin preparing their IRB application materials in advance of the JIT notice.

Approval times will vary based on the level of review needed. Researchers are encouraged to read instructions and forms thoroughly to ensure the most accurate documents are submitted at the start, reducing the amount of administrative correction time. Approval times for the University of Minnesota IRB are posted each quarter.

6. What is the appropriate order for filing amendments at both sites?

Amendments (i.e. changes to objectives, procedures) should follow the same process as the application, as outlined in Question #4, and be submitted in that order.

Please make clear in your modification request at both sites which site the change will mainly impact.

7. What is the best way to communicate changes, significant events, amendments and any other reports to both the University of Minnesota IRB and Minneapolis VA IRB?

For the University of Minnesota IRB:

- *New Study Application*
- *Modifications*
- *Continuing Reviews*
- *Reportable Events*
- *Study Closure*

For the Minneapolis VA IRB, instructions for submissions are found on the VA network at R:\All_Staff\IRBNet.

8. What happens if changes requested at one institution during the review process aren't in line with the other institution? How does that get resolved?

Although infrequent, instances arise in which one IRB requests changes at odds with the other. In these cases, please contact the Minneapolis VA IRB office at IRBMN@VA.GOV and they will work with the University of Minnesota IRB to determine a solution.

9. Is University of Minnesota IRB approval needed if the only work being done there is using the CMRR facilities?

Work conducted at the CMRR is considered to be human subjects research and is under the oversight of the UMN Human Research Protection Program/IRB. At this time, research must be reviewed by both IRBs or an external IRB with which both institutions have a reliance agreement (e.g., Advarra, WCG IRB).

We highly recommend being very clear in your protocol the limited nature of the work being done at the University of Minnesota. The best practice is to use the location selection feature in ETHOS and select other and fill in Minneapolis VA in the location text box.

Protocol templates are available to ensure your proposal as complete and compliant as possible.

10. For complex proposals, is it possible to use an external single IRB, like Advarra?

The use of an external IRB may be more practical in some cases. Note: VA policy prohibits VA funds paying for the use of an external IRB. This includes subaward funds.

11. What training will I need at each institution?

Training requirements differ at the 2 institutions. VA's requirements are found here: https://www.va.gov/MINNEAPOLISRESEARCH/info/Training_required_for_Human_Subjects_Research.pdf. University of Minnesota IRB Training Requirements: https://research.umn.edu/units/irb/education-training.

Contact information:

Minneapolis VA IRB
IRBMN@VA.GOV

University of Minnesota IRB
Request Consultation
irb@umn.edu

If you have questions or feedback about this guidance, please contact irb@umn.edu.